

REMARKS/ARGUMENTS

Status of the Claims

Claims 1-31 were pending. Claims 1 and 18 have been amended, and new claim 32 has been added. Therefore, upon entry of this amendment, which is respectfully requested, claims 1-32 will be pending.

Double Patenting Rejection

Claims 1-17 were provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-3, 7, 8 and 17 of co-pending Application No. 09/691,405. As co-pending Application No. 09/691,405 is now abandoned, this provisional rejection is now rendered moot.

35 USC §103 Rejections

Claims 1-5 and 11-31 were rejected under 35 U.S.C. 103(a) as being obvious by Zimmerman *et al.*, Electrophoresis, 1995, Vol. 16, p. 941-947 (hereinafter "Zimmerman"), in view of Thompson *et al.*, Lupus, 1993, 2, p. 15-19 (hereinafter "Thompson") and Kim *et al.*, IEEE Transactions on Pattern Analysis and Machine Intelligence, 1986, p. 761-765 (hereinafter "Kim"), and further supported by Anderson *et al.*, WO/1999/039298; Filed 03/02/1999 (hereinafter "Anderson"). Claims 6-10 and 22-24 were rejected under 35 U.S.C. 103(a) as being obvious by Thompson in view of Kim and Diamond *et al.* as applied to claims 1-5 and 11-14, above, and further in view of Kopecky, Design and Implementation of the Internet-Based Medical Expert System ToxoNet, 1999, p. 1-153. Applicants respectfully traverse there rejections.

Applicants respectfully assert that the cited references, either individually or in combination, fail to teach or suggest limitations of the claims. For example, the cited references fail to teach or suggest the limitation of "automatically applying a k-nearest neighbor process to the **quantitative** values of the sample data set and the reference data sets to produce a statistically derived decision indicating whether, **out of a range of none, one or more than one of said systemic autoimmune diseases**, the patient test sample is associated with none, one or

more of said specific SADs", where the quantitative values represent levels for "each of a **plurality of specific autoantibodies**" as recited in independent claim 1. (emphasis added) Similar limitations are presented in independent claim 18. It is noted that Thompson teaches qualitative analysis of data, and Zimmerman analyzes Western blots using neural network pattern recognition analysis techniques. One outcome of a quantitative comparison as recited in the claims is that the patient test sample will be found to be clear of the systemic autoimmune diseases (SADs). Another outcome is that the patient test sample will be found to have one of the SADs. Another possible outcome is that the patient test sample will be found to have more than one of the SADs. This is significant because many people do, in fact, fit the definition of more than one disease or have what is called "overlap syndrome", which is a condition where there are symptoms consistent with more than one disease. The cited references, taken individually or in combination, fail to teach or suggest the capacity to provide a statistically derived decision where the outcome indicates which of one or more of the SADs the patient test sample is associated. For example, neural network analysis as taught by Zimmerman, on the other hand, would at best provide a single disease as output. Thus, there is a difference between the claimed invention as recited in claim 1 (and 18) and a combination of the cited references in that there is a capacity to quantitatively determine and identify one **or more** of the SADs. One technical effect of this difference is that a much more complete diagnosis of a patient sample may be performed. For example, a patient sample may be found to have more than one of the SADs in which case further investigations can be made looking for more than one of the SADs.

Accordingly, Applicants respectfully request withdrawal of the rejections to independent claims 1 and 18 for at least the above reasons. Applicants also respectfully request withdrawal of the rejections to all claims depending from claims 1 and 18, based at least on their dependency from claims 1 and 18.

It should be further noted that Applicants do not believe that one skilled in the art would be motivated to combine all the disparate references presented in the above rejections. Also, Applicants believe that such combinations would not result in the claimed invention, or that such combinations would render the claimed invention obvious. Nonetheless, Applicants

will withhold further argument and comment at this time as Applicants believe the pending claims are allowable based at least on the above reasons.

Applicants also assert that the cited references fail to teach or suggest concordance values, and the use of concordance values, as recited in claims 11-16 and 25-31 for example.

Further, Applicants maintain all prior arguments as to why aspects of the present claims distinguish over the cited references, and will readdress those arguments if necessary in an Appeal.

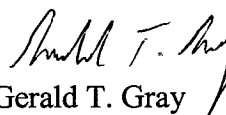
With regard to new claim 32, Applicants assert that the cited references fail to teach or suggest limitations for reasons similar to those presented above. Further, none of the references teach or suggest providing a statistically derived decision as output, where the decision identifies which of the **more than one** of said systemic autoimmune diseases the patient test sample is associated with if the statistically derived decision indicates that the patient test sample is associated with more than one of said systemic autoimmune diseases. Such technology is particularly useful for instances of "overlap syndrome", e.g., where a patient has symptoms consistent with more than one disease.

CONCLUSION

In view of the foregoing, Applicants believe all claims now pending in this Application are in condition for allowance and an action to that end is respectfully requested.

If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at 925-472-5000.

Respectfully submitted,


Gerald T. Gray
Reg. No. 41,797

TOWNSEND and TOWNSEND and CREW LLP
Two Embarcadero Center, Eighth Floor
San Francisco, California 94111-3834
Tel: 925-472-5000
Fax: 415-576-0300
GTG:sea 61685944 v1